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REMARKS

Claims 1-20 are pending. In the Office Action dated March 24, 2004, the Examiner rejected claims 1-20. Applicants have herein amended claims 1 and 10. Support for the amendments may be found at pages 12-14. No new matter has been added. Accordingly, claims 1-20 are pending.

In view of the amendments and the remarks herein, Applicants respectfully request reconsideration and allowance of all claims.

Rejections under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-2 under 35 U.S.C. § 102(b) as being anticipated by Schisler *et al.* (U.S. 6,312,940) ("the '940 patent") or, in the alternative, by Cook *et al.* (U.S. 5,972,689) ("the '689 patent"). In particular, the Examiner stated that Schisler and/or Cook teach identical subject matter to claims 1-2.

Applicants respectfully disagree. A claim is anticipated under § 102(b) only if each and every limitation is disclosed in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 639 (Fed. Cir. 1989) and MPEP § 2131. Claim 1 is directed to a composition comprising about 10^3 cfu to about 10^{11} cfu per gram dry inert carrier of a bacterial strain that exhibits degradative activity towards a toxin. The toxin is selected from the group consisting of polyaromatic hydrocarbons, benzo[a]pyrene, chlorinated aliphatic solvents, mineral oils, petroleum fuel hydrocarbons, aliphatic hydrocarbons, alicyclic hydrocarbons, polychlorinated biphenyls, aromatic hydrocarbons, alcohols, ethers, ketones, herbicides, insecticides, DDT, dieldrin, toxaphene, 1,1,1-trichloroethane, 1,1 dichloroethane, trans-1,2 dichloroethene, trichloroethylene, methylene chloride, toxaphene, dieldrin, lindane, aldrin, chlordane, endrin, endrin aldehyde, heptachlor, heptachlor epoxide, alpha-BHC, beta-BHC, gamma-BHC, delta-BHC, 4,4'-DDD, 4,4'-DDE, 4,4'-DDT, endosulfan I, endosulfan II, and endosulfan sulfate.

The '940 patent discloses the use of *Bacillus* species to reduce *Fusarium* head blight via surface application to cereal heads. The '689 patent discloses seed-treatment compositions

comprising a *Bacillus* strain that is useful for treating three root fungal diseases:

Gaeumannomyces graminis, *Rhizoctonia*, and *Pythium*. The composition is applied directly to seeds or is used as a root dip. See Col. 14, lines 29-33. Applicants respectfully point out that *Fusarium*, *Gaeumannomyces graminis*, *Rhizoctonia*, and *Pythium* are not any of the toxins recited in claim 1. Indeed, at no point do the '940 or '689 patents teach or suggest a composition exhibiting degradative activity towards any toxin, let alone the particular toxins recited in claim 1. Thus, neither the '940 nor the '689 patent can anticipate claims 1-2. Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 103(a)

The Examiner also rejected claims 3-20 under 35 U.S.C. § 103(a) as being unpatentable over the '689 or '940 patents in view of Backman *et al.* (U.S. 5,288,488) ("the '488 patent"); Ito *et al.* (U.S. 6,264,967) ("the '967 patent"); and Allen *et al.* (U.S. 2,552,388) ("the '388 patent"). In particular, the Examiner stated that the '967 patent taught a porous ceramic carrier for use with microbes; that the '488 patent taught fungal pathogens selected from, e.g., *Fusarium* and *Rhizoctonia*; and that the '388 patent taught that creeping bentgrass can be treated with an agent to remedy crabgrass contamination. In sum, the Examiner stated that it would have been obvious to one of ordinary skill in the art to combine the '689 and '940 teachings with the '488, '967, and '388 patents to deliver microorganisms to an environment for elimination of contaminants; that the fungal pathogens were taught by the cited art; and that the '488 patent taught that the compositions can be applied to leaves to remedy "contaminants." The Examiner concluded that "to select for toxins such as toxaphen is well within the purview of an artisan."

Applicants respectfully disagree. Proper analysis under § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed product or carry out the claimed process, and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have had a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As indicated above, neither the '940 nor the '689 patent teaches or suggests a composition exhibiting degradative activity towards a toxin, particularly the toxins recited in claims 1-12. The '488, '967, and '388 patents do not cure the deficiencies of the '940 or '689 patents. None of the cited patents teaches or suggests, either alone or in combination with any other of the cited patents, the use of a composition having about 10^3 cfu to about 10^{11} cfu per gram dry inert carrier of a bacterial strain that exhibits degradative activity towards the recited toxins. In this regard, Applicants first respectfully assert that both the '967 and the '388 patents are nonanalogous art, as neither is in the Applicants' field of endeavor or reasonably pertinent to the problem with which the inventors were concerned. See M.P.E.P. § 2141.01(a). For example, M.P.E.P. § 2141.01(a) notes that differences in structure and function of the invention carry greater weight than PTO classifications in determining whether art is analogous or not. The '967 patent discloses care garments (e.g., sheets, clothes) for eliminating *Staphylococcus aureus* in, e.g., hospital settings. The care garment can include a carrier (e.g., diatomaceous earth, porous ceramics) for immobilizing the microorganism. See Col. 5, line 45 through to Col. 6, line 6. The '967 target *Staphylococcus aureus* pathogens are vastly different from the toxins recited in the present claims, as *Staphylococcus* is a microorganism and the toxins are organic chemicals. Applicants respectfully assert that the present case is an example where "structure and function" differences are of such significance as to support the conclusion that the '967 patent is nonanalogous art. The '388 patent discloses the use of organo-mercuric salts as herbicides, e.g., to inhibit the growth of crabgrass. As with the '967 patent, the '388 target is recognizably different from the presently claimed target pathogen - a plant species (crabgrass) vs. organic chemical toxins. Thus, Applicants respectfully assert that the '388 patent is also nonanalogous art.

Notwithstanding whether the '967 or the '388 patents are nonanalogous art, none of the '967, '488, or '388 patents teach or suggest that one of ordinary skill in the art should modify the compositions of the '940 and '689 patents to result in a composition including a bacterial strain and an inert carrier, where the bacterial strain exhibits degradative activity towards the recited toxins. The '488 patent discloses foliar application of "habitat enhancers" to promote selectively

the growth of a desired microorganism relative to another microorganism. The habitat enhancers can include a polymeric substrate (e.g., chitin, cellulose) which the microorganisms can degrade in certain circumstances. See Col. 10, lines 40-55 and Col. 11, lines 38-63. The '967 patent discloses care garments for eliminating *Staphylococcus aureus*. The care garment can include a carrier (e.g., diatomaceous earth, porous ceramics) for immobilizing the microorganism. The '388 patent discloses the use of organo-mercuric salts as herbicides, e.g., to inhibit the growth of crabgrass. None of the '967, '488, or '388 patents, however, teach or suggest that one of ordinary skill in the art should modify the compositions of the '940 and '689 patents to result in a composition including a bacterial strain and an inert carrier, where the bacterial strain exhibits degradative activity towards one or more of the recited toxins. Indeed, at no point are any of the recited toxins ever mentioned in any of the cited references.

Moreover, there would be no reasonable expectation of success that a modification of the '689 or '940 compositions would yield a composition capable of degrading one or more of the recited toxins. One of ordinary skill in the art would have had no reasonable expectation that topical compositions useful for treating *Fusarium* head blight (the '940 patent) or seed or root dip compositions useful for treating fungal root rot (the '689 patent) could be used successfully to degrade one or more of the recited toxins, given the disclosures of the '967, the '488, and the '388 patents. The recited toxins are organic chemicals, which one of skill in the art would recognize as vastly different in nature than a fungal pathogen, *Staphylococcus aureus*, or crabgrass. Accordingly, Applicants respectfully assert that claims 1-12 are not obvious in view of the cited references and respectfully request withdrawal of the rejections.

With respect to claims 13-20, none of the cited references teach or suggest, either alone or in any combination, a method for identifying an inhibitor of a mammalian pathogenic fungus, where the method includes contacting a Gram-positive bacterium designated APM-1 (ATCC Accession NO. PTA-4838) or an extract therefrom, with the mammalian pathogenic fungus, and measuring whether the growth of the mammalian pathogenic fungus is inhibited. As indicated previously, the cited references are directed to the eradication of plant pathogens (e.g., *Fusarium*, root rot fungi, various plant pathogens set forth at '488 Col. 7); to the inhibition of crabgrass (the

'388 patent); or to the elimination of *Staphylococcus aureus* (the '967 patent). None of the cited pathogens is a mammalian pathogenic fungus. Furthermore, none of the cited methods disclose the contacting of APM-1 with a mammalian pathogenic fungus. Thus, Applicants respectfully assert that the cited art, in any combination, simply cannot suggest to one of ordinary skill in the art to modify any of the cited methods for eradicating, e.g., plant pathogens or crabgrass, to result in a method for identifying an inhibitor of a mammalian pathogenic fungus. One of ordinary skill in the art would recognize that plant pathogens and mammalian pathogenic fungus are very different in nature. One of ordinary skill in the art would, therefore, have had no reasonable expectation that a method for treating a plant pathogen could be successfully modified to yield a method for identifying an inhibitor of a mammalian pathogenic fungus. Accordingly, Applicants respectfully assert that claims 13-20 are not obvious in view of the cited references, and respectfully request withdrawal of the rejections.

In view of all of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103(a).

Applicant : Haim B. Gunner et al.
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Filed : June 23, 2003
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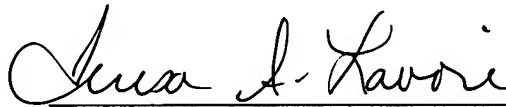
Attorney's Docket No.: 07880-121001 / UMA00-16A

CONCLUSION

Applicants respectfully suggest that all claims are in condition for allowance, which action is requested. The Examiner is invited to telephone the under-signed if such would expedite prosecution. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 6/15/04



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ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Applied Biological Systems
Attn: Ming Coler
P.O. Box 9612
North Amherst, MA 01059-9612

Deposited on Behalf of: University of Massachusetts

Identification Reference by Depositor:

New strain of Bacillus: APM-1

Patent Deposit Designation

PTA-4838

The deposit was accompanied by: ___ a scientific description ___ a proposed taxonomic description indicated above.

The deposit was received December 2, 2002 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

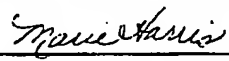
If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested December 6, 2002. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:


Marie Harris, Patent Specialist, ATCC Patent Depository

Date: January 6, 2003

cc: Fish & Richardson P.C.
(Ref: Docket or Case No.: 13623-002P01)

Budapest Treaty Deposits

American Type Culture Collection

10801 University Blvd., Manassas, VA 20110-2209
Phone (703) 365-2700; fax (703) 365-2745; e-mail applied-sci@atcc.org

ATCC

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

ALL QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED.

1. Name of deposit. If microorganism, give complete scientific name including genus and species and source of material; if virus, give name, whether plant or animal, and source including geographic location; if cell line, give tissue and species, geographical source of isolation, and any known hazards associated (HIV, EBV, etc.); if genetic materials, give name of organism from which vector, clone or library is derived, source of the DNA insert identified by species (e.g. human, mouse) or scientific name, and give name of gene and identity of the host organism; if consortia or mixed culture, each component of the mixture must be identified; if seeds, embryos, insect eggs, etc., give common name, scientific name, and geographical source.
Tentatively identified as a new strain of Bacillus. This microorganism
was an isolate from oat bran flour used to culture Metarhizium
anisopliae. Experimental trials provided consistent evidence of its
ability to inhibit growth of a variety of plant pathogens.
2. Strain designation (i.e., number, symbols, etc.) APM-1
The strain designation must correspond with the vial labels.
3. Is this an original deposit under the Budapest Treaty? Yes
4. Is this a request for a conversion of a deposit already at ATCC to meet the requirements of the Budapest Treaty? If so please indicate ATCC designation. No
5. Is this deposit a mixture of microorganisms or cells? No
6. Provide details necessary to cultivate, test for viability, and store deposit. If mixture, provide description of components and a method to check presence. If plasmid, provide name of host and antibiotic resistance.
Culture on Trypticase soy broth.
7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).
Description enclosed.
- a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics.
No
- b. If deposit is hybridoma, what is the isotype of antibody produced? NA
8. Is this strain hazardous to humans? No 1 Animals? No Plants? No. If yes, what is the recommended biosafety level for working with this strain? _____. (Refer to Biosafety in Microbiological and Biomedical Laboratories, 4th ed. U.S. Dept. of Health and Human Services at www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm).
9. Availability: Prior to the issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent patent office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered:
 - a) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued. Yes ____ No X
 - b) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requestors which satisfy patent offices in countries not signatory to the Budapest Treaty? Yes ____ No X
If yes state which countries. _____

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty and your deposit has already been released for distribution due to the issuance of a U.S. patent, you cannot restrict it from further distribution.

After a U.S. patent issues and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under USPTO Rules and Regulations (37 CFR 1.808 [a](2)).

10. ATCC will notify you of your ATCC number after confirmation of viability testing is complete.

Name of individual to notify:

Fax: 413-253-6866

Phone: 413-253-6565

E-mail: mjeolier@yahoo.com

11. Payment by check, or credit card (Mastercard, VISA or American Express), must accompany the deposit unless prior arrangements for billing have been made and approved. ATCC accepts Purchase Orders in the correct amount:

Purchase Order No. _____

Check No. _____

Credit Card number. Please indicate MasterCard, VISA, or AE. VISA 4802 1320 4920 9086

Exp. Date: 09/30/03

Name shown on card: Haim B. Gunner

(Please type or print clearly.)

Haim B. Gunner

Signature of card holder

PAYMENT: ATCC MUST HAVE A BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX NUMBER FOR ALL DEPOSITS:

Ming Coler, Applied Biological Systems, Ltd.

P.O. Box 9612

North Amherst, MA 01059-9612

Phone: 413-253-6565

Fax: 413-253-6866

12. Name, address, telephone and facsimile number of your attorney of record. Fish & Richardson P.C.
225 Franklin Street, Boston, MA 02110-2804; Fax: (612) 288-9696

Phone: (617) 542-5070

(Ref: Docket or Case No. 13623-002P01)

13. **MUST BE COMPLETED.** Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institute and not an individual.) University of Massachusetts

I understand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Ming Coler

Ming Coler

11/25/2002

Typed Name

Signature

Date

Address: P.O. Box 9612, North Amherst, MA 01059-9612

Phone: 413-253-6565

Fax: 413-253-6866

E-mail: mjcoler@yahoo.com

ADDRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Patent Depository
American Type Culture Collection
10801 University Blvd.
Manassas, VA 20110-2209 U.S.A.

STORAGE: Cultures are stored for 30 years from date of deposit or 5 years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

FEES: For current fees, check our Web site at www.atcc.org, request a fee sheet by e-mail to applied-sci@atcc.org, or call (703) 365-2700 ext. 320. All fees are subject to change.

ATCC USE ONLY: ATCC DESIGNATION _____ REC'D _____ V.T. RESULT _____

Name of Deposit _____ Strain Designation: _____

Form BP/1 Rev. 2/00